WHAT IS CLAIMED IS:

1. A bacterial expression system for the production of rhUG comprising a synthetic gene which codes for human UG, wherein the synthetic gene comprises Seq. ID. Nos. 1-4.

2. The expression system of claim 1, wherein the synthetic gene further comprises Met-Ala-Ala at the N terminus of the synthetic gene.

3. A bacterial expression system for production of rhUG comprising a human cDNA sequence which codes for human UG wherein the gene further comprises Met-Ala-Ala at the N-terminus of the sequence.

4. The expression system of claim 3, wherein the expression system further comprises an approximately 2.8 kb par sequence.

5. A method of producing a rhUG research seed bank comprising:

   a. inoculating onto a growth medium at least one colony of a bacterial strain comprising a rhUG expression system;

   b. incubating the inoculated growth medium until a stationary phase is reached;

   c. adding glycerol to the inoculated growth medium;

   d. freezing the culture in aliquot portions; and

   e. storing the frozen aliquot portions at a temperature below about -50 C.

6. The method of claim 5, wherein the inoculated growth medium is incubated until an optical density measured between 550 nm to 660 nm of about 0.8 AU to 1.5 AU is reached.

7. The method of claim 5, wherein the cryopreservative comprises glycerol.

8. The method of claim 5, wherein the aliquot portion is about 1 ml.

9. The method of claim 5, wherein the storage temperature is between about -70 and about -90 °C.

10. A method of producing a rhUG master cell bank comprising:

a. inoculating a suitable incubating broth with an aliquot portion of a rhUG research seed bank to form a bacterial culture;

b. incubating the bacterial culture;

c. adding a cryopreservative to the bacterial culture to form a cryopreserved solution;

d. transferring a portion of the cryopreserved solution to a cryovial; and

e. storing the cryovial at a temperature below about -60 C.

11. The method of claim 10, wherein the culture is incubated until an optical density measured between 550 nm to 660 nm of about 0.8 AU to 1.5 AU reached.

12. The method of claim 10, wherein the cryopreservative comprises glycerol.

13. The method of claim 10, wherein the portion transferred to a cryovial is about 1 ml.

14. The method of claim 10, wherein the storage temperature is between about -70 and about -90 C.

15. A method of producing a rhUG production cell bank comprising:

a. inoculating a suitable incubating broth with an aliquot portion of a rhUG master cell bank to form a bacterial culture;

b. incubating the bacterial culture;

c. adding a cryopreservative to the bacterial culture to form a cryopreserved solution;

d. transferring a portion of the cryopreserved solution to a cryovial; and

e. storing the cryovial at a temperature below about -60 C.

16. The method of claim 15, wherein the bacterial culture is incubated until an optical density measured between 550 nm to 660 nm of about 0.8 AU to 1.5 AU is reached.

17. The method of claim 15, wherein the cryopreservative comprises glycerol.

18. The method of claim 15, wherein the portion transferred to a cryovial is about 1 ml.

19. The method of claim 15, wherein the storage temperature is between about -70 and about -90 C.

20. A method of expressing rhUG comprising the steps of:

a. providing a production seed cell bank culture comprising an expression vector capable of expressing rhUG;

b. inoculating a broth medium with the production seed cell bank culture to form an inoculum;

c. incubating the bacterial culture formed in step b;

d. inoculating a large scale fermenter with the inoculum formed in step c to form a fermentation culture;

e. incubating the fermentation culture within the large scale fermenter;

f. adding an induction agent to the fermentation culture to induce the expression of rhUG; and

g. harvesting the fermentation culture after step f.

21. The method of claim 20, wherein the expression vector comprises Seq. ID Nos. 1-4.

22. The method of claim 20, wherein the inoculum is incubated for a period between about 12 hours and about 24 hours at a temperature between about 28 °C and about 36 °C.

23. The method of claim 20, wherein the large scale fermenter has at least a 300 liter capacity.

24. The method of claim 20, wherein the incubation of step e is continued until an optical density 550 nm to 660 nm until a minimum OD of 2.0 AU is reached.

25. The method of claim 20, wherein the induction agent comprises isopropyl-beta-D-thiogalactopyranoside (IPTG).

26. The method of claim 20, wherein of about 1 to about 4 hours elapses between step f and step g.

27. The method of claim 20, wherein harvesting the fermentation culture comprises centrifugation.

28. A method of expressing rhUG comprising the steps of:

a. inoculating a large scale fermenter with an inoculum comprising an expression vector capable of expressing rhUG to form a fermentation culture;

b. incubating the fermentation culture within the large scale fermenter;

c. adding an induction agent to the fermentation culture to induce the expression of rhUG; and

d. harvesting the fermentation culture.

29. The method of claim 28, wherein the expression vector comprises Seq. ID Nos. 1-4.

30. The method of claim 28, wherein the large scale fermenter has at least a 300 liter capacity.

31. The method of claim 28, wherein the incubation of step b is continued until an optical density 550 nm to 660 nm until a minimum OD of 2.0 AU is reached.

32. The method of claim 28, wherein the induction agent comprises isopropyl-beta-D-thiogalactopyranoside (IPTG).

33. The method of claim 28, wherein of about 1 to about 4 hours elapses between step c and step d.

34. The method of claim 28, wherein harvesting the fermentation culture comprises centrifugation.

35. A method of purifying rhUG comprising the steps of:

a. providing a bacterial cell paste comprising bacterial cells capable of overexpressing rhUG;

b. lysing the bacterial cell paste to form a supernatant;

c. filtering the supernatant formed in step b through a first nominal molecular weight cut off (NMWCO) membrane to form a first permeate;

d. concentrating the first permeate formed in step c by the use of a second NMWCO membrane;

e. loading the concentrated permeate formed in step d onto an anion exchange column to form a first eluate;

f. concentrating the first eluate formed in step e by the use of a third NMWCO membrane to form a second concentrate;

g. loading the second concentrate formed in step f onto a Hydroxyapatite (HA) column to form a second eluate;

h. separating host-derived proteins from the rhUG in the second eluate formed in step g to provide purified rhUG; and

i. recovering the purified rhUG formed in step h.

36. The method of claim 35, wherein the synthetic gene expressed in the bacterial cells comprises Seq. ID Nos. 1-4.

37. The method of claim 35, wherein lysing comprises shearing.

38. The method of claim 35, wherein between step b and step c, cell debris is removed by centrifugation.

39. The method of claim 35, wherein the membrane of step b is about a 30K to 100K NMWCO membrane.

40. The method of claim 39, wherein the filtering of step c comprises the use of a tangential flow filtration (TFF) system.

41. The method of claim 35, wherein the membrane of step d is about a 5K NMWCO membrane.

42. The method of claim 41, wherein the anion exchange column of step e is a Macro Q anion exchange column.

43. The method of claim 41, wherein the host-derived proteins of step h are separated with a Chelating Sepharose Fast Flow (CSFF) resin column.

44. The method of claim 43, wherein the CSFF resin column comprises copper.

45. The method of claim 44, wherein after step h a positively charged membrane is placed downstream of the CSFF column forming a pass through substantially free of host derived proteins.

46. The method of claim 45, wherein the positively charged membrane is a Sartobind Q TFF membrane.

47. The method of claim 35, wherein the second eluate is diafiltered through about a 30K NMWCO membrane.

48. The method of claim 35, wherein the rhUG recovered in step i is substantially free of aggregates.

49. A method of purifying rhUG comprising the steps of:

a. providing bacterial cells capable of overexpressing rhUG;

b. lysing the bacterial cells to form a supernatant liquid;

c. filtering the liquid through a molecular weight cut off (NMWCO) membrane;

d. loading the liquid onto an exchange column;

e. separating host-derived proteins from the rhUG to provide purified rhUG; and

f. recovering the purified rhUG.

50. The method of claim 49, wherein the synthetic gene expressed in the bacterial cells comprises Seq. ID Nos. 1-4.

51. The method of claim 49, wherein the filtering of step c comprises the use of a tangential flow filtration (TFF) system.

52. The method of claim 49, wherein the anion exchange column of step d is a Macro Q anion exchange column.

53. The method of claim 49, wherein the host-derived proteins of step h are separated with a Chelating Sepharose Fast Flow (CSFF) resin column.

54. The method of claim 49, wherein the rhUG recovered in step i is substantially free of aggregates.

55. A method of producing a pharmaceutical grade rhUG drug substance comprising the steps of:

a. providing a bacterial expression system capable of expressing rhUG;

b. inoculating a fermenter with an inoculum comprising the bacterial expression system to form a fermentation culture;

c. adding an induction agent to the fermentation culture to induce the expression of rhUG by the bacterial expression system;

d. harvesting the rhUG expressed in step c; and

e. purifying the rhUG harvested in step d, wherein the purifying step comprises the use of at least one filtration step and at least one exhange column.

56. An assay method for determining the potency of recombinant human uteroglobin in a sample which comprises:
(a) contacting a sample containing recombinant human uterogloblin with phospholipase A_2,
(b) introducing a labeled substrate to said sample,
(c) separating product from sample, and
(d) determining level of cleavage.

57. The method of claim 56, wherein the assay is used in conjunction with a standard ^{14}C-labeled assay.

58. The method of claim 56, wherein the radiolabeled substrate is 1-stearoyl-2-[^{14}C]arachidonyl phosphotidyl choline.

59. The method of claim 56, wherein the recombinant human uteroglobin phospholipase A_2 is added to a final concentration of 2nM to 200nM.

60. The method of claim 56, wherein the sample of step (a) is preincubated for 15 minutes to 30 minutes at 30 °C to 40 °C.

61. The method of claim 56, wherein the reaction in step (b) is stopped by addition of an organic phase stopping solution.

62. The method of claim 56, wherein the sample in step (c) is separated by vortexing and centrifugation.

63. The method of claim 56, wherein the product of step (c) is separated from the sample by liquid-liquid separation.

64. The method of claim 56, wherein the level of cleavage in step (d) is determined by scintillation counting.

65. A method for measuring *in vitro* the anti-inflammatory effect arising from inhibition or blocking of secretory phopsholipase A_2 enzymes by recombinant human uteroglobin, comprising:

(a) contacting a sample containing recombinant human uterogloblin with phospholipase A_2,

(b) introducing labeled substrate to said sample,

(c) separating product from sample, and

(d) determining level of cleavage by scintillation counting.

66. An assay method for assaying for the inhibition of secretory phopsholipase A_2 activity by recombinant human uteroglobin, comprising:

(a) contacting a sample containing recombinant human uterogloblin with phospholipase A_2,

(b) introducing labeled substrate to said sample,

(c) separating product from sample, and

(d) determining level of cleavage by scintillation counting.

67. An assay method for determining the potency of recombinant human uteroglobin in a sample which comprises:

(a) contacting a sample containing recombinant human uterogloblin with phospholipase A_2,

(b) introducing flourescently labeled substrate to said sample,

(c) separating non-cleaved substrate from sample, and

(d) determining amount of cleaved substrate by flourescence.

68. The method of claim 67, wherein the sample of recombinant human uteroglobin in step (a) has a final concentration of 34nM to 34μM.

69. The method of claim 67, wherein the sample of step (a) is preincubated for about 15 to 30 minutes at about 30 to 40 °C.

70. The method of claim 67, wherein the flourescently-labeled substrate is 2-decanoyl-1-(O-(11-(4,4-difluoro-5,7-dimethyl-4-bora-3a,4a-diaza-s-indacene-3 propionyl)amino)undecyl)-sn-glycero-3-phosphotidylcholine.

71. The method of claim 67, wherein the reaction in step (b) is stopped by addition of an organic phase stopping solution.

72. The method of claim 67, wherein in step (c) 1μL to 100 μL of the stopped assay is loaded directly onto a silica normal phase HPLC column.

73. A method for measuring *in vitro* the binding of recombinant human uteroglobin to fibronectin, comprising:

(a) contacting a recombinant fragment of human fibronectin with a recombinant human CC10-HRP conjugate,

(b) visualizing the assay to determine binding of recombinant human uteroglobin to the fibronectin fragment.

74. A method for determining the purity of recombinant human uteroglobin which comprises,

(a) taking samples of intermediates at each step within the process of claim 35 and

(b) analyzing the process intermediates.

75. The method of claim 74, wherein process intermediates are analyzed by SDS-PAGE.

76. The method of claim 74, wherein process intermediates are analyzed by rhUG ELISA.

77. The method of claim 74, wherein process intermediates are analyzed by LAL.

78. The method of claim 74, wherein process intermediates are analyzed for protein content.

79. A pharmaceutical composition comprising the purified recombinant human uteroglobin of claim 35.

80. A pharmaceutical composition comprising a purified recombinant human uteroglobin and a pharmaceutically acceptable carrier or diluent.

81. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin contains less than 5% aggregates of recombinant human uteroglobin.

82. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin has a purity of greater than 95%.

83. The pharmaceutical composition of claim 80 wherein endotoxin levels within said recombinant human uteroglobin comprises less than 5 EU/mg rhUG.

84. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is in a sodium chloride solution.

85. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable in solution at 4 °C for at least 4 months.

86. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable in solution at 4 °C for at least 6 months.

87. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable in solution at 4°C for at least 9 months.

88. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable in solution at 4 °C for at least 12 months.

89. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable in solution at 4°C for at least 15 months.

90. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable in solution at 4 °C for at least 18 months.

91. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable is solution at 25 °C and 60% Room Humidity for at least 1 month.

92. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable is solution at 25 °C and 60% Room Humidity for at least 2 months.

93. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable is solution at 25 °C and 60% Room Humidity for at least 4 months.

94. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is stable is solution at 25 °C and 60% Room Humidity for at least 7 months.

95. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is safe to administer to a mammal.

96. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is safe to administer to a human.

97. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is safe to administer via an intratracheal tube.

98. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is safe to administer to a premature infant.

99. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is safe to administer to a patient receiving artificial surfactant.

100. The pharmaceutical composition of claim 80 wherein said recombinant human uteroglobin is safe to administer to a patient in respiratory distress.